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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,118	06/23/2003	A. Satyanarayan Naidu	50046290-0017	9093
24982	7590	09/21/2005	EXAMINER	
KENNETH J. HOVET NORDMAN, CORMANY, HAIR & COMPTON P.O. BOX 9100 1000 TOWN CENTER DRIVE OXNARD, CA 93031-9100			RUSSEL, JEFFREY E	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 09/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/602,118

Applicant(s)

NAIDU, A. SATYANARAYAN

Examiner

Jeffrey E. Russel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 September 2005 and 05 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 18-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9-11 and 20 is/are allowed.
- 6) ☒ Claim(s) 1-8, 12-16, 18 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1. The claim for priority set forth at page 1, lines 6-8, of the specification is objected to because: (1) The filing date given for parent application 09/980,062 is incorrect. The correct filing date is May 10, 2002. (2) The status of parent application 09/322,700 needs to be updated in the priority claim. Correction is required.

2. Claims 2-8 and 12-14 are objected to because of the following informalities: At claim 2, line 3, a comma should be re-inserted after "abony". Appropriate correction is required.

3. The terminal disclaimer filed January 5, 2005 is approved.

4. Instant claims 1-8, 12-16, 18, and 19 are not deemed to be entitled under 35 U.S.C. 120 to the benefit of the filing date of parent application 09/980,062 because the parent application '062, under the test of 35 U.S.C. 112, first paragraph, does not disclose possible contamination by *Listeria*, *Campylobacter*, *Hafnia*, *Aeromonas*, *Micrococcus*, *Achromobacter*, *Proteus*, *Brocothrix*, *Arcobacter*, *Shewanella*, *Deinoccus*, *Flavobacterium*, *Acinetobacter*, *Cladosporium*, *Mucor*, *Rhizopus*, *Penicillium*, *Geotrichium*, *Sporotrichium*, *Candida*, *Torula*, or *Rhodotorula* species in general, or by *A. butzleri*, *P. fluorescence*, *S. putrefaciens*, *E. cloa*, *F. aquatile*, *A. Baumannii*, or *A. calcoaceticus* species in particular, does not disclose treating a ready-to-eat meat product, does not disclose treating bologna or pepperoni, does not disclose treating a meat product additionally containing a vegetable, dairy, sauce, broth, or gravy ingredient, and does not disclose further treating a food or meat product with at least one other microbiological decontamination intervention such as with ozone, thermal pasteurization, high pressure processing, electrolyzed oxidizing water, ionizing radiation, or an antimicrobial agent.

Instant claims 9-11 and 20 are deemed to be entitled under 35 U.S.C. 120 and 35 U.S.C. 371 to the benefit of the filing date of parent application 09/980,062 and of PCT/US00/14818,

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because the parent application '062 and the parent PCT application, under the test of 35 U.S.C. 112, first paragraph, discloses the claimed invention. Accordingly, the WO Patent Application 00/72690 and Naidu (U.S. Patent No. 6,172,040) are not available as prior art against claims 9-11 and 20.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 1-8, 13, 14, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 00/72690. The WO Patent Application '690 teaches reducing microbial contamination of a composition by treating with lactoferrin immobilized on a naturally occurring substrate via the N-terminus region of the lactoferrin. The composition to be treated can be a meat product, including beef, pork, poultry, and vegetable products; primal, subprimal, and case-ready cuts; chops, steaks, ground meat, and cold cuts; and sausages, salamis, and hotdogs. The microbes include verotoxic E. coli and L. monocytogenes. The lactoferrin concentration on the surface of the composition to be treated ranges from about 0.0001 to about 10 mg/sq. inch. See, e.g., page 28, lines 1-15, and claims 18, 32, 33, 38, 39, 57-61, 68, and 69.

7. Claims 12 and 19 are rejected under 35 U.S.C. 103(a) as being obvious over the WO Patent Application 00/72690. Application of the WO Patent Application '690 is the same as in the above rejection of claims 1-8, 13, 14, and 18. The WO Patent Application '690 does not teach treating a frozen meat product additionally containing a vegetable, dairy, sauce, broth, or gravy ingredient. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to treat frozen meat products additionally containing a vegetable, dairy, sauce, broth, or gravy ingredient, because the treatment of the WO Patent

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Application '690 is applicable to all foodstuffs, including meat and vegetable products; because frozen meat products additionally containing a vegetable, dairy, sauce, broth, or gravy ingredient are known in the art; and because it is desirable to prevent or reduce microbial contamination of such products.

8. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being obvious over the WO Patent Application 00/72690 as applied against claims 1-8, 13, 14, and 18 above, and further in view of Reimann et al (U.S. Patent No. 6,291,003), Yuan et al (U.S. Patent No. 6,066,348), or Newman (U.S. Patent No. 5,597,597). The WO Patent Application '690 does not teach additional treatment of the food or meat products with at least one other microbiological decontamination intervention such as with ozone, thermal pasteurization, high pressure processing, electrolyzed oxidizing water, ionizing radiation, or an antimicrobial agent. Reimann et al teach pasteurizing meat in order to reduce surface contamination. See, e.g., the Abstract. Yuan et al teach disinfecting a foodstuff such as meat using ozone. See, e.g., the abstract and claims 1 and 15. Newman teaches sterilizing meats with UV radiation. See, e.g., column 4, lines 25-36, and Example 3. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to combine the method for reducing microbial contamination of meat products of the WO Patent Application '690 with the pasteurization, ozone treatment, and/or UV radiation of Reimann et al, Yuan et al, and/or Newman because pasteurization, ozone treatment, and UV radiation are known methods for decontaminating meat products and because the use of plural different types of decontaminating procedures would ensure that a wider variety of contaminants are removed and that they are removed to a greater degree.

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9. Claims 1-8, 13, 14, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Naidu (U.S. Patent No. 6,172,040). Naidu teaches reducing microbial contamination of a composition by treating with lactoferrin immobilized on a naturally occurring substrate via the N-terminus region of the lactoferrin. The composition to be treated can be a meat product, including beef, pork, and poultry products; sliced deli meats and ground meat; and sausages, salamis, and hotdogs. The microbes include verotoxic *E. coli* and *S. dysenteriae*. The lactoferrin concentration on the surface of the composition to be treated ranges from about 0.0001 to about 10 mg/sq. inch. See, e.g., column 5, line 18 - column 6, line 15. With respect to instant claim 18, because the food and meat products taught by Naidu are the same as those claimed by Applicant, the food and meat products taught by Naidu are inherently subject to contamination by *Listeria monocytogenes* to the same extent claimed by Applicants. Note that the instant claims do not require actual contamination by any particular microbe.

10. Claims 12 and 19 are rejected under 35 U.S.C. 103(a) as being obvious over Naidu (U.S. Patent No. 6,172,040). Application of Naidu is the same as in the above rejection of claims 1-8, 13, 14, and 18. Naidu does not teach treating a frozen meat product additionally containing a vegetable, dairy, sauce, broth, or gravy ingredient. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to treat frozen meat products additionally containing a vegetable, dairy, sauce, broth, or gravy ingredient by the method of Naidu, because the treatment of Naidu is applicable to all foodstuffs, including meat and vegetable products; because frozen meat products additionally containing a vegetable, dairy, sauce, broth, or gravy ingredient are known in the art; and because it is desirable to prevent or reduce microbial contamination of such products.

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11. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being obvious over Naidu (U.S. Patent No. 6,172,040) as applied against claims 1-8, 13, 14, and 18 above, and further in view of Reimann et al (U.S. Patent No. 6,291,003), Yuan et al (U.S. Patent No. 6,066,348), or Newman (U.S. Patent No. 5,597,597). Naidu does not teach additional treatment of the food or meat products with at least one other microbiological decontamination intervention such as with ozone, thermal pasteurization, high pressure processing, electrolyzed oxidizing water, ionizing radiation, or an antimicrobial agent. Reimann et al teach pasteurizing meat in order to reduce surface contamination. See, e.g., the Abstract. Yuan et al teach disinfecting a foodstuff such as meat using ozone. See, e.g., the abstract and claims 1 and 15. Newman teaches sterilizing meats with UV radiation. See, e.g., column 4, lines 25-36, and Example 3. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to combine the method for reducing microbial contamination of meat products of Naidu with the pasteurization, ozone treatment, and/or UV radiation of Reimann et al, Yuan et al, and/or Newman because pasteurization, ozone treatment, and UV radiation are known methods for decontaminating meat products and because the use of plural different types of decontaminating procedures would ensure that a wider variety of contaminants are removed and that they are removed to a greater degree.

12. Claims 1-6 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Laufer (U.S. Patent No. 5,106,643) in view of the Harper et al text, Okonogi et al (U.S. Patent No. 4,791,193), and the Naidu et al article (Env. Nutr. Interactions, Vol. 2, pages 35-50). Laufer teaches whole milk in combination with meat products such as beef or pork. The beef can be ground beef. See, e.g., Examples 3 and 30. The Harper et al text teaches that milk inherently

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comprises casein, triglycerides, lactose (a disaccharide comprising galactose), α -lactalbumin, IgA, lysozyme, and nucleic acids in an aqueous solution. The Harper et al text also teaches that milk inherently comprises citrate, phosphate, and carbonate buffer salts. Okonogi et al teach that lactoferrin is inherently present in milk (see column 1, lines 11-25). Because the same components are present in the same aqueous solution, inherently the lactoferrin which is present in the milk of Laufer will be immobilized on the casein, triglycerides, lactose, α -lactalbumin, IgA, lysozyme, and nucleic acids which are inherently present in milk of Laufer to the same extent claimed by Applicant. The Naidu et al article teaches that lactoferrin complexes with casein, α -lactalbumin, lysozyme, and IgA (see page 45, first full paragraph), and thus is further evidence that the milk of Laufer inherently comprises immobilized lactoferrin. Note that the rejected claims do not require the lactoferrin to be in isolated form, and thus embrace lactoferrin as it naturally occurs in milk. Because the meat products taught by Laufer are the same as those claimed by Applicant, the meat products taught by Laufer are inherently subject to contamination by the same microbes and to the same extent claimed by Applicants. Note that the instant claims do not require actual contamination by any particular microbe. Because the same meat products are being contacted with the same immobilized lactoferrin, inherently microbial contamination of the meat products in Laufer will be reduced to the same extent claimed by Applicant. The Naidu et al article also teaches that lactoferrin blocks the growth of *B. subtilis*, *E. coli*, *S. dysenteriae*, and *C. albicans* (see the paragraph bridging pages 38 and 39), and thus is further evidence that the lactoferrin present in the milk of Laufer inherently will reduce microbial contamination by these microbes. Sufficient evidence of similarity is deemed to be present

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between the method of Laufer and Applicant's claimed method to shift the burden to Applicant to provide evidence that the claimed invention is unobviously different than that of Laufer.

13. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being obvious over Laufer (U.S. Patent No. 5,106,643) in view of the Harper et al text, Okonogi et al (U.S. Patent No. 4,791,193), and the Naidu et al article (Env. Nutr. Interactions, Vol. 2, pages 35-50) as applied against claims 1-6 and 18 above, and further in view of Reimann et al (U.S. Patent No. 6,291,003), Yuan et al (U.S. Patent No. 6,066,348), or Newman (U.S. Patent No. 5,597,597). Laufer does not teach treatment of the food products with at least one microbiological decontamination intervention such as with ozone, thermal pasteurization, high pressure processing, electrolyzed oxidizing water, ionizing radiation, or an antimicrobial agent. Reimann et al teach pasteurizing meat in order to reduce surface contamination. See, e.g., the Abstract. Yuan et al teach disinfecting a foodstuff such as meat using ozone. See, e.g., the abstract and claims 1 and 15. Newman teaches sterilizing meats with UV radiation. See, e.g., column 4, lines 25-36, and Example 3. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to treat the food products of Laufer with the pasteurization, ozone treatment, and/or UV radiation of Reimann et al, Yuan et al, and/or Newman because pasteurization, ozone treatment, and UV radiation are known methods for decontaminating food products and would result in a food product which is safer to consume.

14. Applicant's arguments filed January 5, 2005 have been fully considered but they are not persuasive.

With respect to the prior art rejections based upon the WO Patent Application 00/72690 as the primary reference, Applicant contends that the reference is not prior art as a result of

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Applicant's priority claim. The examiner agrees with respect to claims 9-11 and 20, and the WO Patent Application '690 and Naidu (U.S. Patent No. 6,172,040) are no longer applied against these claims. The examiner does not agree that the remainder of the claims are entitled under 35 U.S.C. 120 to the benefit of the filing date of parent application 09/980,062. See the effective filing date analysis set forth in section 8 of the first Office action and repeated in section 4 above. Applicants have not traversed this analysis. Accordingly, the WO Patent Application '690 and Naidu are available as prior art under 35 U.S.C. 102(b) against instant claims 1-8, 12-16, 18, and 19. With respect to priority claims and effective filing date analyses, see MPEP 201.11(VI).

The anticipation rejection based upon Laufer (U.S. Patent No. 5,106,643) in view of the Harper et al text, Okonogi et al (U.S. Patent No. 4,791,193), and the Naidu et al article (Env. Nutr. Interactions, Vol. 2, pages 35-50) is maintained. Applicant contends that Laufer does not teach a defined dispersion, and states that a defined dispersion "is a composition whose constituents and their concentrations are known". Initially, the examiner does not agree with Applicant's definition of "defined dispersion" as set forth in his arguments. "Defined dispersion" is defined at page 8, lines 2-4, of the specification, and this definition is silent as to whether the concentrations of constituents in a defined dispersion are known or not. Secondly, working with the specification definition that a "defined dispersion" is a "dispersion... of preselected ingredients or components, each in preselected amounts", the milk of Laufer does satisfy the specification definition of "defined dispersion". Milk is the preselected ingredient of Laufer, and it is used in preselected amounts. See, e.g., Examples 3 and 30. Finally, Applicant contends that all of the components and component concentrations of the milk of Laufer are not known, and that therefore the milk can not constitute a defined dispersion. However, throughout

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Applicant's specification, Applicant exemplifies components of a defined dispersion whose component and component concentrations are not and can not be known. For example, Applicant acknowledges at page 5, lines 13-24, that lactoferrin varies with respect to sequence length, degree of glycosylation, and sequence identity. At page 4, lines 21-23, and page 6, lines 18-24, Applicant exemplifies substrates, e.g., collagen, gelatin, casein, mucin, heparan sulfate, carrageenan, and galactose-rich polysaccharides, which are heterologous products whose individual components and component concentrations are never known exactly. With respect to the defined dispersion exemplified in Example 2 of the parent application, the example does not attempt to completely define the composition of the lactoferrin or of the galactose-rich polysaccharides. A definition can not be attributed to "defined dispersion" which Applicant's exemplified compositions fail to meet.

15. Claims 9-11 and 20 are allowed.

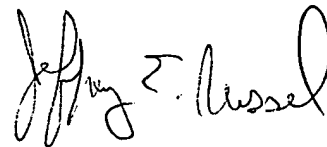
16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (703) 872-9306; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

A handwritten signature in black ink, appearing to read "Jeffrey E. Russel". The signature is fluid and cursive, with the first name "Jeffrey" and last name "Russel" clearly distinguishable.

Jeffrey E. Russel

Primary Patent Examiner

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JRussel

September 16, 2005